

Questions from the HIT Policy Committee / Information Exchange Workgroup:

General Questions:

1. What are the technology impediments to the electronic exchange of lab data?

There are no pure technological impediments to laboratory data exchange, but there are no universal standards, making the technology more complicated and costly than it should be. The technology exists right now and is in use throughout the industry. The main impediment is that no one has compelled the industry to adopt a standard. Even the standards that have been adopted, such as Health Level 7 (HL7), are not implemented in a standard format. Each vendor has a different HL7 format such that they are not interpreted in the same way by all vendors. Systemized Nomenclature of Medicine (SNOMED) codes have also been somewhat of a breakthrough but are problematic as often being “too expressive” (Shortliffe, Perreault, Widerhold, & Fagan, pp. 228,229). Conversely ICD-9 codes were not expressive enough thus leading to ICD-9-CM (clinical modifications). Note that ICD-10 does not yet have CM codes (Shortliffe, Perreault, Widerhold, & Fagan, p. 226). Regardless, these are dictionary shortcomings, not technological.

Since messaging standards are still not widely adopted, interfaces still require feasibility studies, specification negotiations, and lengthy user configuration to develop an interface between foreign systems. The Health Information Standards Technology Panel (HISTP) appears to be moving this effort along.

2. What are the business case impediments to the electronic exchange of lab data?

Patient laboratory data must be portable from one care setting to another. The Personal Health Record (PHR) is an excellent way for lab data to be viewed across providers' settings. If all providers fed data into the PHR, there would be summary data possessed by the patient, which would decrease the ordering of unnecessary tests. Direct data transfer, either through an EHR-to-EHR model or through a PHR model, would support data exchange. The current climate of ordering labs on patients to generate revenue may in fact prevent the support of national laboratories from supporting the electronic exchange of laboratory data. If a provider were to be able to obtain a useful lab result performed elsewhere, why order additional labs on that patient?

A low ROI for small labs is a compelling reason to not invest in data exchange. Conversely, it is in the industries' best financial interest to block any standards and encourage proprietary data exchange. If the industry continues to be proprietary only the patients and providers lose out, and the cost of these proprietary data exchanges are passed to the consumer. Unless external force is applied, lab vendors will be proprietary. Consider in West Virginia that several FTE's spend time scanning or typing in results into the lab system because the proprietary interface to any non-LabCorp labs is too costly to build. We spent \$60K to build a bidirectional interface to LabCorp, but any labs ordered outside of LabCorp are received and entered manually because additional interfaces proved too difficult and costly to build.

3. What are the operational impediments to the electronic exchange of lab data?

Compelled compliance to an already robust standard such as LOINC (Logical Observation Identifiers Names and Codes) is key to facilitating true interoperability and data exchange.

A standard vocabulary for laboratory tests would be very helpful for the electronic exchange of laboratory data. Adoption of LOINC, UCUM, and SNOMED will greatly simplify the exchange and aggregation of lab data. Keeping a local test dictionary up-to-date with standard codes would be further simplified by standardizing and restricting the creation of new local, user-defined laboratory test definitions.

Operationally setting up dictionaries, training, maintaining, and deploying the system is key. LOINC codes go a long way towards a standard compendium. They have been in existence in excess of 10 years yet are not widely used in the industry. Some vendors simply won't ever embrace LOINC codes. LOINC has worked with the European committee for standardization (CEN) to create a more comprehensive list of observations. From an operational standpoint, there are no current national/international standards in existence for laboratory information systems' vendors to adhere to when designing/programming LIS systems, thereby preventing the facilitation of the electronic exchange of laboratory information.

One of the challenges that interfaces may have is to positively identify a patient record. Reliable and accurate identification is key to patient-centric exchange of lab data. One of the first operations that an interface program must do is determine if a unique patient record already exists in a foreign system for the patient, in which case the record would be updated. If there is not patient record, a new record may be created. A patient cannot be identified by name alone. Other identifiers such as a patient record number or SSN or other demographics are used to ensure that the labs are placed in the correct patient's database/chart. Work that is being done on a master patient index will largely address this issue.

4. What are the regulatory impediments to the electronic exchange of lab data?

CLIA, HIPAA and individual state laws are all regulatory impediments. HIPAA slows down the work on creating interfaces because there are many restrictions on access and viewing patient data.

Laboratory Electronic Data Interchange (LEDI) has to be agile regarding new components. CLIA is more concerned with the quality of results than the exchange. The current regulatory environment for the exchange of laboratory data slows the process of exchanging data down to a crawl. A broader discussion needs to occur regarding the regulatory laws currently in place to facilitate the exchange of lab data.

5. What is the low-hanging fruit for improving electronic exchange of lab data?

Standardization of messaging and vocabulary with clear interpretations on restrictions for lab data access (while working on interface implementation) would greatly improve the ability to create interfaces, and exchange/aggregate data. Compelling use of a standard language would facilitate exchange.

6. What's a priority to facilitate easier/broader electronic exchange of lab data, even if not immediately actionable?

Standard vocabularies for test orders, test units, and test results.

The RPMS system is beginning to implement LEDI, LOINC, and a HL7. Unfortunately each commercial vendor believes they have the best practices. However, standardized tests across an enterprise, use of LOINC codes, standard output streams that can be used for cumulative reports or electronic warehousing exist. Systems must also handle code set versioning to track when a LOINC changes, for example. When there are updates to codes, there should be a way to track the old codes and compare them to the new codes. As reference ranges change for lab tests, one should be able to see what the range was 10 years ago compared to today.

7. What best practices would you recommend in this area?

LOINC (Logical Observation Identifiers Names and Codes), UCUM (Unified Codes for Units of Measurements), and SNOMED (Systemized Nomenclature of Medicine).

8. What work-arounds for these impediments have you experienced/designed/ observed?

There are not any good work-arounds that solve the problems introduced as impediments to exchange of data. The fact that there are not good work-arounds further exemplifies the need for standardization to eliminate the barriers. One example of an institution dealing with this issue is the VA. The VA locked down its laboratory test definitions to simplify LOINC mapping.

Most impediments in the commercial world are solved by purchasing a proprietary interface engine that takes data from multiple streams and produces an HL7 or other user specified output.

Many entities that need results for legitimate purposes are not listed as “authorized persons” for the purpose of receiving test results directly from the lab vendor. Examples include health plans, QIOs, non-ordering providers, and RHIOs. There are not sufficient work-arounds to address the sharing of meaningful data across the health care system.

Specific Questions:

9. Has your State’s definition of “authorized person” limited the ability of health care entities to exchange lab data electronically?

Yes.

10. How do you, your laboratory or EHR vendor view the requirements set forth in 42 C.F.R. § 493.1291 (Requirement that the test results and other patient-specific data are accurately and reliably sent from the point of data entry to final report destination, in a timely manner)? For example, technical method or visual “eye-ball” inspection of every terminal/interface in an installation to ensure that data is displayed correctly.

As defined as a requirement through the College of American Pathology (CAP) lab data received through an electronic exchange must be verified prior to the final destination in the medical record. To achieve this, Resource Patient management System (RPMS-- the EHR used by the Indian Health Service and by my clinic) returns each result to a verification file for review by a clinical staff member. The vendor is required to return a paper result to the facility in addition to the electronic exchange. The designated clinical staff member compares the electronic data against each paper result. Once the data is verified it is released to the medical record for review by the ordering clinician.

RPMS also has an integrated 'incomplete' file that allows for clinical staff members to

view any accessioned test that has not had a returned result. This allows the facility to contact the vendor in the case of missing results.

By using a standard terminal emulator, and computers that meet stated specs, the output is reasonably assumed as displaying correctly on one or all similarly configured machines. For RPMS data is passed via an API to windows designed and coded by a contract partner. The keys are to assure the IT people know the min specs. Further, a robust error trapping system alerts site managers to problems that need to be examined.

11. How do you, your vendor, or State interpret “final report destination?”
Does this interpretation hinder the electronic exchange of lab data?

The final report destination, or legal medical record, is in our case the RPMS EHR database. This does not hinder data exchange at all and in fact encourages it. The lab result goes back to the EHR where the ordering provider placed the request/order.

12. Do you believe that the adoption of a universal compendium/dictionary will reduce costs related to the implementation of lab interfaces and improve electronic exchange?

Yes, this would be a big help for the implementation and maintenance for laboratory data exchange. There is no good reason not to move in this direction. This will reduce the time to build custom dictionaries and interface engines dramatically.

13. Who is best suited to maintain a universal compendium?

CMS

14. What standards, if any, would you recommend for the electronic transmission of lab data?

Standards set forth by HITSP, HL7 and LOINC working together.

15. How do you ensure lab data is transmitted securely and confidentially?

Standards set forth by HITSP. By using VPN, SSH, or tunneling.

16. What are the obstacles preventing patients from receiving copies of their lab data?

Sarah Chouinard (Provider)

HIPAA is a barrier in that the rules about who can receive data have made it difficult to send and communicate results.

There are cultural impediments such as clinicians' desire to interpret labs for patients and physical barriers such as not having technology (computers) in patients' homes. Patients' laboratory results must be clearly explained to the patient by the appropriate patient provider. Any usable PHR should have a place for providers to add comments to lab results placed in the PHR as part of the CCR (continuity of care record). If clinicians could comment on labs before releasing them to a PHR, patients could receive labs in a timely manner and have comments from the ordering clinician as they are perusing their results.